REMARKS

Entry of the foregoing, reexamination and further and favorable reconsideration of the subject application in light of the following remarks, pursuant to and consistent with 37 C.F.R. § 1.112, are respectfully requested.

By the foregoing amendment, claims 1 and 3 have been amended to recite "[a] method for treating bronchial asthma by inhibiting the accumulation of eosinophiles in cells, tissues or a body . . . ." Support for this amendment can be found throughout the originally filed application. See, for example, page 11, line 20 through page 12, line 26. Claim 3 has been further amended in accordance with the Examiner's suggestion as discussed below. Claims 2 and 4-16 have been canceled without prejudice or disclaimer to the subject matter recited therein. Applicant reserves the right to file one or more divisional and/or continuation applications directed to any of the cancelled subject matter. Additionally, new claims 18-19 have been added. Support for these new claims can also be found at, for instance, page 11, line 20 through page 12, line 26. No new matter has been introduced by way of the above amendments.

I. Requirement for Information

The Examiner has propounded, pursuant to 37 C.F.R. § 1.105, an interrogatory of facts known to applicant. In making a requirement for information under 37 C.F.R. § 1.105, the Examiner is supposed to "state why the requirement has been made and how the information is necessary to the examination." M.P.E.P. 704.14(a). In this instance, the Examiner has not provided these requisite statements.

Nonetheless, the Examiner has asked applicant to "provide, if known, the amount of pelargonidin which is present in a black rice which was extracted by methods instantly disclosed." OFFICE ACTION DATED AUG. 7, 2007, at 2. Upon information and belief, the information requested is unknown and/or is not readily available to applicant.

II. Response to Claim Objections

The Examiner has objected to claim 3 for certain informalities. By the present amendment, claim 3 has been amended such that the period appears at the end of the formula and, as suggested by the Examiner, the phrase "wherein Formula 1 is represented by the following" is inserted before the formula. Such amendments are believed to obviate the Examiner's objections.

Claim 8 has been objected to under 37 C.F.R. § 1.75(c) for allegedly being of improper dependent form for failing to further limit the subject matter of a previous claim. Claim 8 has been canceled, without prejudice or disclaimer, by the present amendment. Thus, the Examiner's objection is rendered moot.

III. Response to Rejections Under 35 U.S.C. § 112

Claims 1, 3, 7-8 and 17 have been rejected under 35 U.S.C. § 112, first paragraph, as purportedly failing to provide enablement for the full scope of the invention as claimed. Applicant respectfully traverses this rejection.

The Examiner has admitted though that the application is enabled for a method for "treating allergic disease, particularly those recited in claim 7 . . . ." OFFICE ACTION DATED AUG. 7, 2007, at 5. Thus, to expedite prosecution in the present application and not to acquiesce to the Examiner's rejection, claims 1 and 3 have been amended to recite"[a] method for treating bronchial asthma . . . ."

Accordingly, withdrawal of the rejection under 35 U.S.C. §112, first paragraph is believed in order and hence requested.

Claim 8 has been rejected under 35 U.S.C. § 112, second paragraph, as purportedly being indefinite. As described above, claim 8 has been canceled, without prejudice or disclaimer to the subject matter recited therein.

Therefore, the rejection under 35 U.S.C. § 112, second paragraph, has been rendered moot.

IV. Response to Rejections Under 35 U.S.C. §§ 102 and 103

(a) Claims 1 and 17 have been rejected under 35 U.S.C. § 102(b) as purportedly being anticipated by Kim et al. (1999). This rejection is respectfully traversed.

The present application discloses using black rice extract to treat bronchial asthma by inhibiting the accumulation of eosiniphiles. This was confirmed by the inventor in the Examples of the present application and the attached Declaration.

It is well established that, for prior art to be anticipatory, every element of the claimed invention must be disclosed in a single item of prior art in the form literally defined in the claim. *See* M.P.E.P. 2131. This requirement for anticipation has not been met with respect to the present claims of the subject application.

The Kim et al. reference teaches that the methanol extract of *Oryza sativa* L. subsp. Hsien Ting possesses strong anti-anaphylactic activity by inhibition of histamine release from mast cells *in vivo* and *in vitro*. However, Kim et al. does not teach that black rice extract has activity for treating bronchial asthma, nor does Kim et al. teach treating bronchial asthma by inhibiting the accumulation of eosinophiles in the cells, tissues or body of an individual.

Asthma is a respiratory disease characterized by three major symptoms: airway hyper-reactivity, airway obstruction, and lung inflammation. *See* D. W. Jeong et al., *The Journal of Biological Chemistry,* 277(20):17871-76, at 17871, left column, line 1-3 (2000) (submitted with IDS filed concurrently herewith). It is known that the induction of inflammation by increasing Th2 cell type cytokines and eosinophil infiltration into lung play an important role in the pathogenesis of asthma. *See* C. Kroegel et al., *Eur Respir J.* 9:899-904, at 899, left column, line 21-24 (1996) (submitted with IDS filed concurrently herewith); Romagnai S., *J. Allergy Clin. Immunol.* 105:399-408, at 402, right column, line 19-37 and at 403, left column, line 20-23 (2000) (submitted with IDS filed concurrently herewith). Therefore, in order to treat asthma, inhibition of inflammation induced by Th2 cell type cytokines and eosinophil is more important than inhibition of histamine release.

Anaphylaxis shows distinguishable symptoms from asthma. Anaphylaxis is mediated by immunoglobulin E (IgE) and is caused by the release of mast cell and basophil immune mediators. *See* Tang, Angela W. et al., *American Academy of Family Physicians,* 68:1325-32, at 1325, left column, line 7-10 (2003) (submitted with IDS filed concurrently herewith).

As shown in Table 1 below, the symptoms of asthma and anaphylaxis are distinguishable.

<Table 1> Asthma vs. Anaphylaxis

	Asthma	Anaphylaxis
symptoms	Airway hyper-reactivity, airway obstruction, lung inflammation	angioedema, urticaria, laryngeal edema, hypotension, flush, myocardial ischemia, vomiting, nausea, wheezing, diarrhea, abdominal pain, pruritus
immune reactor	Th2 cell	IgE
effector cell	Eosinophil	Mast cell and basophil
mediator	IL-3, IL-4, IL-5, IL-9, IL-10, IL-13, ICAM-1, VCAM-1, E-selectin, NF-kB	platelet activating factor, prostaglandins, leucotrienes, tryptase, kinins, heparin, chymase, TNF-a, IL-1, Nitric oxide, histamine

Since the Kim et al. reference does not teach treating bronchial asthma and does not teach treating bronchial asthma by inhibiting the accumulation of eosinophiles in the cells, tissues or body of an individual, it can not anticipate the claimed invention. Therefore, withdrawal of the Examiner's rejection under 35 U.S.C. § 102(b) is respectfully requested.

(b) Claim 3 has been rejected under 35 U.S.C. § 102(b) as purportedly being anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Nair et al. (WO 01/15553). This rejection is respectfully traversed.

The Nair et al. PCT publication fails to teach or suggest every element of the claimed invention. In particular, Nair et al. teaches a dietary food supplement that could be used to inhibit inflammation mediated by cyclooxygenase. The claims of the present invention, on the other hand, are directed to a method of treating bronchial asthma by inhibiting the accumulation of eosinophiles in the cells, tissues or body of an individual. Thus, not only

does the Nair et al. PCT publication fail to teach every element of the claimed invention, Nair et al. also fails to suggest that an effective amount of pelargonidin represented by Formula 1 could be used to treat bronchial asthma by inhibiting the accumulation of eosinophiles in the cells, tissues or body of an individual.

Therefore, the Nair et al. PCT publication fails to anticipate and/or render obvious the claimed invention. As such, withdrawal of the examiner's rejection is respectively requested.

(c) Claims 1, 7-8, and 17 have been rejected under 35 U.S.C. § 103(a) as purportedly being unpatentable over Kim et al. (1999) and Assem (1973). This rejection is respectfully traversed.

As discussed in Section IV(a), *supra*, the Kim et al. reference fails to teach using the black rice extract for treating bronchial asthma as well fails to teach using the black rice extract to treat bronchial asthma by inhibiting the accumulation of eosinophiles in cells, tissues or a body. The Assem reference does not remedy the serious deficiencies of Kim et al.

Assem teaches that bronchial asthma due to immediate-type allergy to various allergens may be treated by administering antihistamines or inhibitors of anaphylactic mechanism. However, Assem does not teach how to treat bronchial asthma due to the accumulation of eosinophils.

Bronchial asthma due to immediate-type allergy to various allergens and bronchial asthma due to the accumulation of eosinophils have different processes. Bronchial asthma due to the accumulation of eosinophils belongs to late-phase reaction. *See* Grzegorz Cieslewicz et al, *J. Clin. Investig.*, 104(3):301-308, at 307, left column, line 9-10 (1999) (submitted with IDS filed concurrently herewith). Mechanistically, early-phase reaction ("EPR") and late-phase reaction ("LPR") probably reflect different processes, as the EPR is

blocked by nedocromil, albuterol, and cromoglycate, and the LPR is abolished by nedocromil, cromoglycate, and steroids when given before allergen provocation. Although the EPR appears to depend largely on the release of mediators from airway mast cells, leading to bronchoconstriction and airway edema, the development of the LPR and the concomitant increases in airway reactivity are associated with an influx and activation of inflammatory cells, particularly lymphocytes and eosinophils in the bronchial mucosa. *See* Grzegorz Cieslewicz et al, *J. Clin. Investig.*, 104(3): 301-308, at 301, left column, line 10-22 (1999). The LPR response to three agents (Albuterol, Cromoglycate, Hydrocortisone) administered before OVA provocation is different from the EPR response to three agents. *See* Grzegorz Cieslewicz et al, *J. Clin. Investig.*, 104(3):301-308, at Fig 4 and at 305, left column, line 33 - right column, line 12 (1999).

The pharmacological mechanism and treating agent of bronchial asthma due to immediate-type allergy to various allergens are different from those of bronchial asthma due to the accumulation of eosinophiles. Thus, even if the Kim et al. reference is combined with the Assem reference, the combination fails to arrive at the claimed invention of the present application. As such, a proper case of *prima facie* obviousness has not been established. Withdrawal of the Examiner's rejection under 35 U.S.C. § 103 is therefore respectfully requested.

CONCLUSION

In view of the foregoing, further and favorable action in the form of a Notice of Allowance is believed to be next in order. Such action is earnestly solicited.

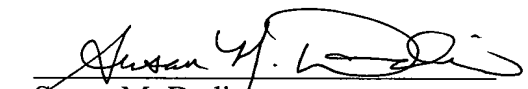
In the event that there are any questions relating to this Amendment and reply, or the application in general, it would be appreciated if the Examiner would telephone the undersigned attorney concerning such questions so that prosecution of this application may be expedited.

The Director is hereby authorized to charge any appropriate fees that may be required by this paper, and to credit any overpayment, to Deposit Account No. 02-4800.

Respectfully submitted,

BUCHANAN INGERSOLL & ROONEY PC

Date: February 7, 2008

By: 
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